

OBJECTIVE: The objective of this study was to document the clinical and economic characteristics of ambulatory family medicine patients receiving antidepressant medications.

METHODS: The medication profiles of the electronic medical records (EMR) of all Family Medicine patients at the Medical College of Georgia were evaluated. Only patients prescribed an antidepressant drug within the previous 6 months were reviewed. Patient records were reviewed in the order in which they were entered into the EMR system.

RESULTS: The electronic records of 116 patients were reviewed by the same physician researcher. Demographic and clinical data for 89 (76.7%) female and 27 (23.3%) male patients were evaluated. The mean age for these patients was 46.5 years. Sixty-two (53.4%) patients were white, 38 (32.8%) were black. Although usually considered risk factors for the development of depression, marital status and the use of alcohol were not noted in 47 (40.5%) and 62 (53.4%) patients, respectively. The most common comorbid conditions were hypertension (47.4%), gastroesophageal reflux disease (GERD) (20.7%), arthritis (20.7%), anxiety (18.1%), diabetes mellitus (17.2%), and pain syndromes (45.7%). Thirty-one (26.7%) patients, received amitriptyline. Twenty-two (71%) received less than 50 mg per day. Fourteen (12%) patients received two antidepressants, most often an SSRI in the morning with a sedating agent at bedtime. Of the 26 patients with available financial data, 25 patients paid a co-payment of \$5.00 or less.

CONCLUSIONS: Antidepressant drugs are frequently prescribed in primary care patients with multiple comorbid conditions (mean 3.9).

PMH3

COST-EFFECTIVENESS OF FLUVOXAMINE IN THE TREATMENT OF RECURRENT DEPRESSION IN FRANCE

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OBJECTIVE: The objective of this study was to examine the cost-effectiveness of fluvoxamine compared to treatment with tricyclic antidepressants (TCAs) in patients who suffer depressive episodes.

METHODS: The setting for this study was France. A Markov process model was constructed to model the effectiveness, as measured by time without depression, and the costs of both treatments. The model examined a period of 18 months in order to capture the influence of both relapses and recurrences on the outcomes. Data for the construction of the model came from the published literature, an expert panel, and a large multicenter randomized clinical trial. Costs were obtained from published sources.

RESULTS: The results of the baseline analysis showed that the use of fluvoxamine in the maintenance treatment

(recurrence prevention) of depressive disorders was less costly than TCAs with total costs (direct and indirect costs) of 40,232.40 FF versus 52,257.53 FF, respectively. In addition, due to the prevention of relapse and recurrence, effectiveness fluvoxamine was favored, as it was associated with a longer period of time without depression when compared to therapy with TCAs: 79% of the study period compared to 71% for TCAs. Sensitivity analyses confirmed the robustness of these findings.

CONCLUSION: In conclusion, based on the assumptions used in the model, the use of fluvoxamine as maintenance therapy is clinically and economically justified in patients with depressive disorders.

PMH4

THE BUDGET IMPACT PHARMACOTHERAPY SELECTION FOR MAJOR DEPRESSIVE DISORDER: A MULTINATIONAL STUDY

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OBJECTIVE: We conducted a multinational pharmacoeconomic evaluation of treatment for major depressive disorder (MDD) to assess the potential budget impact of changes in antidepressant prescribing patterns in Canada, Germany, Italy, the Netherlands, Poland, Spain, Sweden, Switzerland, the United Kingdom, the United States, and Venezuela.

METHODS: The analysis compared the serotonin-norepinephrine reuptake-inhibitor (SNRI), extended-release venlafaxine, to selective serotonin reuptake-inhibitors (SSRIs) and tricyclic antidepressants (TCAs). A meta-analysis was performed to determine the clinical rates of success, defined as a 50% reduction in depression scores on the Hamilton Depression Scale (HAM-D) or the Montgomery-Asberg Depression Rating Scale (MADRS). Treatment regimen costs were determined from standard lists, fee schedules, and communication with local health economists in each country. We included data from 48 studies on 4,690 patients in the meta-analysis. The meta-analytic rates were applied to decision analytic models to calculate expected cost and expected outcomes for each comparator. Cost-effectiveness was determined using expected values for both a successful outcome (as defined by the meta-analysis), and a composite measure of outcome termed "Symptom-Free Days." A policy analysis was conducted to examine the budgetary impact on the health system, in each country, of increasing the utilization of the most effective comparator.

RESULTS: Treatment of MDD with extended-release venlafaxine yielded the highest overall efficacy rates for outpatients (73.7%) and inpatients (62.3%). Extended-release venlafaxine had the highest failure rate due to lack of efficacy (5.3%) and adverse drug reactions (11.3%). Initiating treatment of MDD with extended-release venlafaxine yielded the lowest expected cost for outpatients

in 9 of the 11 countries studied, and for inpatients in 10 of the 11 countries studied. The weighted average expected cost per patient for MDD treatment varied from US \$642 (Poland) to US \$5,825 (US). The estimated budgetary impact to the primary payer for each 1% of utilization of extended-release venlafaxine ranged from US \$61,640 (Switzerland) to US \$1,565,900 (Germany) for each 1 million population.

CONCLUSIONS: Policy-makers should implement measures to increase the utilization of cost-effective antidepressant treatment such as extended-release venlafaxine.

PMH5

COST OF ALZHEIMER'S DISEASE CARE IN THE UNITED KINGDOM

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OBJECTIVE: To assess the relationship between illness severity and costs of care in noninstitutionalized patients with Alzheimer's Disease in the United Kingdom.

METHODS: In this cross-sectional, multicenter analysis, Alzheimer's Disease patients cared for in the community (128), their caregivers (128), and 56 matched controls were recruited chronologically and interviewed once to establish resource use over the previous 3 months. Patients were stratified into three severity groups according to their cognitive function as assessed by their Mini Mental State Exam score. Costs were calculated from the perspective of society as a whole.

RESULTS: Over the 3-month period, total mean cost per control subject (£387) was minor compared with the mean cost incurred by patients with mild (£6,616), moderate (£10,250), and severe (£13,593) Alzheimer's Disease. Indirect cost, mainly time spent by caregivers, was the main cost component in all groups (68.6%), followed by direct medical costs (24.7%).

CONCLUSION: The cost of care for an Alzheimer's Disease patient is substantial and is directly related to the severity of the patient's illness.

PMH6

DEVELOPMENT OF A NEW DISEASE-SPECIFIC QUALITY OF LIFE SCALE FOR USE IN SCHIZOPHRENIA

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OBJECTIVE: To develop a health-related quality of life questionnaire to measure the effects of treatment on the quality of life of people with schizophrenia, the Schizophrenia Quality of Life Scale (SQLS).

METHODS: A standardized state-of-the-art methodology has been used for the development of the SQLS. Items were generated from in-depth interviews with 20 patients and eight health professionals. From a list of 440 statements, a pilot questionnaire containing 80 items was developed by a panel of experts. The pilot questionnaire was tested on 20 patients, which resulted in some wording changes. A sample of 161 patients completed the 80-item questionnaire. A factor analysis using Varimax rotation was then conducted. This identified 31 questions tapping three factors: psychological, motivational, and physical symptoms. The psychometric properties of the SQLS were then assessed using the following methodology. Sixty-five patients were given the SQLS to complete, along with the following measures: the SF-36, the Hospital Anxiety and Depression Scale (HADS), and the General Health Questionnaire (GHQ-12). A clinical assessment using the Clinical Global Impressions and the Health of the Nation Outcome Scales (HONOS) was made by a psychiatrist. A subset of the patients was asked to complete the SQLS for a second time to assess the reproducibility of the measure.

RESULTS: The validity and reliability of the scale are good.

CONCLUSIONS: The SQLS is now available for use, although further studies of its psychometric properties are ongoing.

PMH7

CROSS-CULTURAL ADAPTATION OF THE INTERNATIONAL INDEX OF ERECTILE FUNCTION (IIEF) IN 31 COUNTRIES

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With the increase of QoL assessment in clinical trials, it is necessary to have cross-culturally valid instruments to make comparisons of health status outcomes and pool data across countries. The IIEF is a 15-item instrument designed in English to assess erectile dysfunction. Prior to use in an international trial, it underwent cross-cultural adaptation in 31 languages. This involved the recruitment of a QoL specialist in each target country. Two independent forward translations were produced by native speakers, bilingual in English. These were reconciled and back-translated into English. The translations were tested for comprehension in a sample target population, compared and internationally harmonized. The developer clarified concepts underlying each item. Translation was difficult, especially when selecting equivalent response categories and appropriate equivalents of common English structures and expressions. The difficulty of the translation and its acceptability depended on the comparability of the original and the target language and culture. Because English is flexible, it was possible to accept "Most of the times (much more than half of the time)" as an answer to the question: "How often have you felt sexual desire in